

Lot: 0130618

HENAN LIHUA PHARMACEUTICAL CO., LTD.

CERTIFICATE OF ANALYSIS

PRODUCT	HYDROCORTISONE ACETATE		DATE OF SAMPLING	APR.24.2018
BATCH NUMBER	K06M20180410M		DATE OF REPORT	MAY.21.2018
BATCH SIZE	146.34Kg		MANUFACTURING DATE: APR.10.2018 RETEST DATE: MAR.2023	
CRITERIA : EP9				
NAME OF THE TEST (METHOD)		SPECIFICATION	RESULTS	
APPEARANCE		WHITE OR ALMOST WHITE CRYSTALLINE POWDER	WHITE CRYSTALLINE POWDER	
IDENTIFICATION	A:IR(2.2.24)	CONFORM	CONFORM	
	B:HPLC	CONFORM	CONFORM	
SPECIFIC OPTICAL ROTATION (2.2.7)		+158° ~ +167°	+165°	
RELATED SUBSTANCES(2.2.29)		IMPURITY A ≤ 0.5% IMPURITY B ≤ 0.3% IMPURITY C ≤ 0.6% IMPURITY D ≤ 0.3% IMPURITY E ≤ 0.3% IMPURITY G ≤ 0.15% UNSPECIFIED IMPURITY ≤ 0.10% TOTAL ≤ 1.5%	IMPURITY A: <0.05% IMPURITY B: 0.11% IMPURITY C: 0.20% IMPURITY D: <0.05% IMPURITY E: 0.10% IMPURITY G: <0.05% UNSPECIFIED IMPURITY: <0.05% TOTAL: 0.41%	
LOSS ON DRYING(2.2.32)		≤0.5%	0.1%	
ASSAY(2.2.29)		97.0%~102.0% (ON DRIED SUBSTANCE)	98.1%	
CONCLUSION: CONFORMS TO EP9				
RESIDUAL SOLVENTS		METHANOL ≤ 3000PPM ACETONE ≤ 5000PPM METHYLENE CHLORIDE ≤ 600PPM DMF ≤ 880PPM	19 PPM 703 PPM NOT DETECTED 326PPM	
MICRONIZED: 90% < 20μm				
STORAGE: STORE IN AN AIRTIGHT CONTAINER. PROTECTED FROM LIGHT				

CHECKER

2018.5.21

QC DIRECTOR

2018.5.21

ADDRESS: MIDDLE OF HUANGHE STREET, ANYANG HI-TECH INDUSTRY DEVELOPMENT ZONE, HE NAN, CHINA

TEL.: +86-372-2595136 +86-372-2595137

FAX: +86-372-2595138